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Attorney Docket No. 25619-501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Schoenfeld *et al.*		
SERIAL NUMBER:	09/806,400	EXAMINER:	Ronald Schwadron
FILING DATE:	March 30, 2001	ART UNIT:	1644
FOR:	COMPOSITIONS FOR THE PREVENTION AND/OR TREATMENT OF ATHEROSCLEROSIS		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DROR HARATS UNDER 37 C.F.R. §1.132

I, Dror Harats, of 71 Mendes Street, 53 765 Ramat Gan, Israel, declare and state that:

1. I am a coinventor, together with Yehuda Shoenfeld and Jacob George, in the above-referenced patent application.

2. I received an M.D. degree from the Hebrew University Hadassah Medical School, Jerusalem, Israel. I worked as a post-doctoral fellow at the University of California at San Francisco from 1991-1994.

3. I am presently employed as the head of the "Institute of Lipids and Atherosclerosis" at the Sheba Medical Center in Tel-Hashomer, Israel. I am an Associate Professor of Medicine at the Sackler School of Medicine, Tel-Aviv University, Tel-Aviv, Israel. I also serve as the Secretary of the Israeli Society for Research, Prevention and Treatment of Atheroclerosis, and drafted the Guidelines for Prevention of Cardiovascular Diseases in Israel, and am a member in good standing of the European Taskforce for Prevention and Treatment of Atherosclerosis and Cardiovascular Diseases.

4. My research focuses on atherosclerosis. Since the beginning of my career, I have published over 80 scientific articles in highly regarded journals and books, and have presented my achievements at many international scientific conferences.

5. I have reviewed the Office Action dated March 3, 2006. I understand that Claims 14 and 28 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the specification does not disclose how to use the claimed method to treat or prevent atherosclerosis in humans *in vivo* using an oral tolerance inducing amount of oxidized LDL. The pending claim is not directed to the induction of oral tolerance, rather, it is directed to a method of treating atherosclerosis by oral administration of an enteric coated tablet or granule composition comprising isolated human oxidized LDL.

6. The specification provides an example in a mouse model (as described in the Specification at, *e.g.*, page 15, lines 20-29; and page 18, line 18 to page 19, line 31). I assert that the LDLR deficient mice used in the studies disclosed in the present application, as well as the more recent studies, provided in the previous declaration, is a preferred, art-recognized model for atherosclerosis, as described in my previous declarations and supported by the state of the art.

   Specifically, it is well recognized in the art that the LDLR deficient mouse is one of the preferred animal model to evaluate the effects of pharmacologic agents on atherosclerosis. LDLR deficient mice, under appropriate conditions, develop complex atherosclerotic lesions and provide practical atherosclerotic mouse models and are the most utilized model to study lipids and atherosclerosis..

7. I further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

Dror Harats

Signed this 31 day of August, 2006